REMARKS

Applicant requests reconsideration and withdrawal of the requirement for restriction. The stated basis for the restriction requirement is that whereas claim 64 requires the step of heating the gripping element to a temperature above the martensite to austenite phase transition temperature, the gripping device of claim 53 can be used without heating the gripping element and returning it to a non-deformed condition. Applicant submits that structural limitations of claim 53 that clearly have no purpose other than to facilitate the method of claim 64 should be given weight in determining whether restriction is appropriate. In this case, claim 53 requires that the gripping element be at a temperature below the martensite to austenite phase transition temperature and that upon heating the gripping element to above the martensite to austenite phase transition temperature the gripping element returns to the non-deformed condition. Unless the gripping element used in the method of claim 64 is used to grip the article when the gripping element is at a temperature below the martensite to austenite phase transition temperature, the method recited in claim 64 cannot be completed. Applicant submits that on this basis the inventions are not distinct under MPEP 806.05(h). Further, based on the fact that claim 53 refers explicitly to the result of heating the gripping element to a temperature above the martensite to austenite phase transition temperature, applicant submits that a method that does not involve heating the gripping element is not a legitimate method of using the product for the purpose of MPEP 806.05(h) analysis. Ignoring the purpose of an essential feature of a product claim would prevent any product and process of using from being shown to be indistinct, which is clearly not the case, since any product, suitably packaged, could be considered to be a paperweight.

Applicant has added a new claim 75 which omits the step of heating the gripping element to a temperature above the martensite to austenite phase transition temperature. The new claim 75 therefore links claim 64 and 53. Consequently, claims 64-75 should be examined with claims 53-63.

Claims 53-63 stand rejected under 35 USC 102 or 35 USC 103 over Bendel et al.

The present invention, as defined in claim 53, is concerned with a biocompatible gripping device for surgical use. The gripping device includes a deformable gripping element comprising a shape memory material having an austenitic phase and a martensitic phase and having shape memory properties in the martensitic phase. Claim 53 recites that the gripping element is at a temperature below the martensite to austenite phase transition temperature, i.e. is in the martensitic phase. In the event that the gripping element is deformed by gripping an article, the gripping element can be returned to its non-deformed condition by heating to a temperature above the martensite to austenite phase transition temperature.

Bendel et al discloses a suture needle holder for endoscopic use. The needle holder has jaws with nitinol inserts I. As noted previously, nitinol can exist in two distinct forms, one being the shape memory form (the martensitic phase) and the other being the superelastic form (the austenitic phase). Bendel et al does not refer to nitinol as being a shape memory alloy or to the transition between the austenitic form and the martensitic form. Bendel et al states at column 3, lines 56-63 that the nitinol "has a low modulus of elasticity and a high yield strength. This combination allows the inserts to deform around the needle ... After the needle is released from the holder, the insert I resumes its original shape..." In order for the insert I to resume its original shape after release, the nitinol must be in the superelastic form, not the shape memory form.

The austenite to martensite phase transition temperature of nitinol is highly dependent on composition. In order for the inserts I of Bendel et al to behave in the manner described, the composition of the nitinol must be selected so that the phase transition temperature is below the temperature at which the needle holder is used and consequently the nitinol is in the austenitic phase, in which it exhibits superelastic characteristics. If we assume that the temperature in a typical operating room is in the region of 60° F (about 15° C), the transition temperature of the nitinol employed by Bendel et al would have to be below 15° C and the nitinol would have to contain more than 50 atomic % nickel.

With regard to the rejection under 35 USC 102, the examiner has not shown that the insert I of Bendel et al is in the martensitic phase. Bendel et al discloses that the insert I resumes its original

shape spontaneously after the needle is released from the holder, and does not disclose or suggest that the insert I undergoes deformation that is reversed by heating the insert. Therefore, it is in fact clear that the insert I is in the austenitic phase, not the martensitic phase. Since the insert I of Bendel et al is at a temperature above the martensite to austenite phase transition temperature, applicant disagrees with the examiner's statement that the insert I "inherently requires to be heated to a temperature above the martensite to austenite phase transition temperature to return it to the non-deformed condition."

The examiner states:

> [T]he gripping element, when used in a cold environment ... would inherently remain in its deformed condition after releasing the article since it would be in the martensite phase. Further, it would inherently return to its non-deformed condition upon heating (to room temperature for example) since heating it would change its state from the martensite to austenite.

How the insert I would behave under the conditions stated by the examiner is not relevant to patentability of claims 53-63 because Bendel et al does not disclose or suggest that the insert I should be used below the martensite to austenite phase transition temperature.

The examiner further asserts that it would have been obvious that the insert I requires to be heated to a temperature above the martensite to austenite phase transition temperature to return it to the non-deformed condition, but the accuracy of this statement is not at issue in evaluating patentability of claim 53. What is at issue is whether Bendel et al discloses or suggests that the insert I is in the martensitic phase.

In view of the foregoing, it is submitted that claim 53 is patentable. It follows that the dependent claims 54-63 also are patentable.

With regard to the rejection of claim 54, since the examiner acknowledges that the insert I of Bendel et al is in the austenitic phase at room temperature the phase transition temperature of the insert I must be below room temperature. Since normal room temperature is well below 50° C, there is no basis for suggesting that it would have been obvious to select the composition of the nitinol such that the martensite to austenite phase transition temperature is

between 50° C and 100° C. Therefore, claim 54 is patentable independently of claim 53.

With respect to claim 58, the phase transition temperature of nitinol containing 48 atomic % nickel and 52 atomic % titanium is higher than 50° C. The insert I of Bendel et al contains more than 50 atomic % nickel. For the reasons presented in connection with claim 54, it would not have been obvious to a person of ordinary skill in the art to have manufactured the insert I of Bendel et al from a titanium nickel alloy having substantially 52 atomic % titanium and substantially 48 atomic % nickel. Applicant therefore submits that claim 58 is patentable independently of claim 53.

Claim 75 is patentable for the reasons presented in support of claim 53. Since claim 64 is narrower is scope than claim 75, it follows that claims 64-74 also are patentable.

Respectfully submitted,

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